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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/544,683 04/07/00 JACOBS

A 99471 US

HM12/0727

EXAMINER

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PORTNER, V

ART UNIT	PAPER NUMBER
1645	<i>Q</i>

DATE MAILED: 07/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/544,683	Applicant(s) Jacobs et al
Examiner Portner	Art Unit 1645

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the normal statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three (3) months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.781(b).

Status

1) Responsive to communication(s) filed on Jul 9, 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7, 9, 10, and 12-14 is/are pending in the application.

4a) Of the above, claim(s) 4-7, 10, and 12-14 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3 and 9 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-7, 9, 10, and 12-14 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office Action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-89)

16) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review Request

17) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement (PTO-1449) Paper No(s). _____

20) Other: _____

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DETAILED ACTION

Claims 1-7, 9-10, 12-14 are pending.

Claims 8 and 11 have been canceled.

Claims 4-7, 10, 12-14 are withdrawn from consideration.

Claims 1-3 and 9 are under consideration.

Election/Restriction

1. Claims 4-7, 10, 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II-IV, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

2. Applicant's election with traverse of Group I, claims 1-3 and 9 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that claims 12-13 should be examined as it would not place a serious burden on the examiner. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

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Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups II-IV are drawn to distinct inventions which are related as separate products and methods using different reagents capable of separate functions. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-IV are classified separately necessitating different searches of issued US Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example antibodies can be made by more than one method, which utilizes different means, specifically chimeric antibodies can be made recombinantly or through immunization and the method of making antibodies can make more than one type of antibody composition based upon the type strain of *Campylobacter* used.

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Additionally, it is submitted that the inventions of Groups I-IV have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group. For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

Sequence Compliance

3. The instant Application is now in sequence compliance.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

5. The information disclosure statement filed April 7, 2000 has been considered.

Drawings

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

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Claim Rejections - 35 U.S.C. § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 recite the phrase "characterized in that". Does this phrase define a process step, is it intended to define the type of antibodies contained in the claimed vaccine or does it define the source of antigen to induce the antibodies ? The meaning of this phrase is not clear. Clarification is requested.

Claim 3 recites the term "R2". Is the term "R2" an arbitrary label ? What characteristics does this strain have that other flagellaless strains do not have? The meaning of this term is not distinctly claimed. Clarification is requested.

Claim 9 depends from claim withdrawn from consideration and therefore is vague and indefinite.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Please Note: The claimed vaccine compositions are being read as compositions of antiserum to the *Campylobacter* antigens, wherein the antigen is a flagellaless antigen (claims 1-3) or antibodies an antigen of *Campylobacter* (claim 9). The recitation of the word “vaccine” is being viewed as recited intended use.

10. Claims 1-2 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Blaser et al (1986).

The claimed invention is directed to a vaccine composition of antiserum directed to a flagellaless of *Campylobacter jejuni* strain (claims 1-2). An additional embodiment claimed is directed to a vaccine that comprises antibodies to an antigenic protein of *Campylobacter* (claim 9). The term vaccine is being viewed as a recitation of intended use.

Blaser et al disclose a flagellaless strain of *Campylobacter* used to produce an antiserum in a host (see page 48, col. 1, paragraph 3, middle of paragraph, F⁺M⁺). The whole cell flagellaless *Campylobacter* strain comprised the antigens shown Figure 1, page 48, col. 2 and was used to produce the antibody containing antiserum. From Figure 1, page 48, it can be seen that

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the flagellin antigen is missing, but other antigens are present, to include all of the antigen present in the whole cell antigen lane (labeled F⁻ M⁻ / WC). The antibodies were isolated and an antisera obtained (see page 50, line 1). By all comparable data, the antiserum comprised the now claimed antibodies. The prior art inherently anticipate the now claimed compositions.

Since the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein antibodies of the prior art does not possess the same functional characteristics of the claimed protein antibodies). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

11. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Dolby et al (1986).

The claimed invention is directed to a vaccine composition of antiserum induced to a flagellaless *Campylobacter jejuni* antigen, wherein the antigen lacks the flagella antigen. The vaccine antiserum composition does not contain antibodies to *Campylobacter* flagellin, wherein the antiserum is able to provide protection against *Campylobacter* infection.

Dolby et al disclose a vaccine composition antiserum that comprised antibodies obtained through immunization with a flagellaless strain of *Campylobacter*, (see abstract, page 144, vaccines section, strain SF-2,(aflagellate)). The antiserum was administered to a young animal

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and provided protection against a homologous strain of *Campylobacter* (see abstract, and page 146, SF-2, Table 2).

The antiserum was also isolated from the host through obtaining sera and assayed for antibody titers, or stored at -20 degrees C (see page 145, paragraph 4). The flagellaless strain did not induce any antibodies to flagellin (see Table 3, page 147, Fla⁻, animal cage numbers 65, 97 and 88).

The flagellaless *Campylobacter jejuni* strain would induce antibodies to all immunogenic antigens produced by *Campylobacter jejuni* except flagella. By all comparable data, the antiserum comprised antibodies that inherently anticipate the now claimed vaccine composition of antibodies.

Since the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein antibodies of the prior art does not possess the same functional characteristics of the claimed protein antibodies). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

12. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Cawthraw et al (1994).

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The claimed invention is directed to a vaccine composition of antibodies obtained from a flagellaless strain of *Campylobacter jejuni*, wherein the strain is called R2. The term "vaccine" is being viewed as a recitation of intended use.

Cawthraw et al disclose anti-*C. jejuni* IgG antibodies induced to a strain of *Campylobacter jejuni* referred to as R2, a flagellaless strain of *Campylobacter jejuni*.

The antigen induced an immune response in chickens (see page 344, col. 2, second paragraph). The antiserum containing antibodies was passively administered to young chicks, wherein antibodies were found in uninfected 1 week old birds, which indicates the presence of maternal antibodies acquired during egg development (see page 347, col. 1, last paragraph).

The isolated antiserum containing antibodies induced to *C. jejuni* R2 inherently anticipate the now claimed invention (Figure 2, page 345).

Since the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein antibodies of the prior art does not possess the same functional characteristics of the claimed protein antibodies). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

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13. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Blaser et al (February 1993).

The claimed invention is directed to a vaccine composition that comprises antibodies to a *Campylobacter* antigen.

Blaser et al disclose a vaccine composition of antibodies induced to a *Campylobacter* antigen. The antibodies were formulated into a vaccine composition and administered to an animal to provide protection against challenge with a pathogenic strain of *Campylobacter*. The antibodies administered provided partial protection against lethal challenge and therefore functioned as a vaccine.

Inherently the vaccine composition of antibodies of Blaser et al anticipate the now claimed invention. Since the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein antibodies of the prior art does not possess the same functional characteristics of the claimed protein antibodies). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

14. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Kervella et al (August 1993).

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The claimed invention is directed to a vaccine composition that comprises antibodies to an antigen of *Campylobacter*.

Kervella et al disclose a composition of antibodies to an outer membrane antigen of *Campylobacter jejuni* referred to as P92 (see page 3447, col. 2, last three lines).

Inherently the antibodies of Kervella et al anticipate the now claimed vaccine composition of antibodies directed to an antigen of *Campylobacter*. Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states “Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer. “The Court further held that “this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art”.

Since the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein antibodies of the prior art does not possess the same functional characteristics of the claimed protein antibodies). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

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Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
16. Blaser et al (US Pat. 5,874,300; 5,470,958) are cited to show *Campylobacter jejuni* antigens
17. Berg et al (1979) is cited to show passive immunization of cows with antibodies against *Campylobacter*.
18. Chan et al (US Pat. 6,087,105) is cited to show a protein associated with *Campylobacter jejuni* invasion.
19. Konkel et al (US Pat. 6,156,546) is cited to show fibronectin binding protein of *Campylobacter jejuni*.
20. Stolle et al (US Pat. 4,748,018) is cited to show passive immunization of mammals with avian antibodies.
21. Diaz Barroso A.et al (1991) is cited to show monoclonal antibodies to *Campylobacter jejuni* outer membrane proteins.
22. Grant et al (1993) is cited to show two flagellaless strains of *Campylobacter jejuni*, and the antigens present in the strain (see page 1767, Figure 2).
23. Griffiths et al (1992) is cited to show antibodies to *Campylobacter* porin.
24. Guerry et al (1990) is cited to show a strain (VC167-B3) that is flagellaless(see sentence bridging pages 1855-1856).

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25. Guerry et al (1997) is cited to show non-lipopolysaccharide surface antigens of *Campylobacter* species.
26. Heaton (Lancet, 1993) is cited to show oral immunoglobulin treatment for *Campylobacter jejuni* infection.
27. Husu et al (1993) is cited to show hyper immune bovine colostrum against *Campylobacter jejuni*.
28. Kinsella et al (1997) is cited to show a *Campylobacter coli* flagellaless strain (see page 4651, col. 1, second paragraph and first sentence second column).
29. Nachamkin et al (1993) is cited to show a flagellaless mutant of *Campylobacter jejuni* (see Table 1, page 1272).
30. Page et al (1988) is cited to show that *C.coli* and *C.jejuni* (flagellate and aflagellate strains) produce identical sucrose gradient fractionation and protein patterns upon SDS-PAGE, save the lack of flagellin (see page 2929, paragraph 1, second half of paragraph).
31. Russell et al (1994) is cited to show an aflagellate variant of strain 81-176(see page 3775, col. 1, first paragraph and abstract; page 3778, col. 2, paragraph 2)
32. Wassenaar et al (1991, 1993; 1994) teach a *Campylobacter jejuni* flagellaless strain, wherein the strain is R2 for the purpose of evaluating flagella and flagellaless strains for colonization of a host.

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33. Wassenaar et al (1997) is cited to show antibodies to a *Campylobacter jejuni* antigens of about 54 and 68 kDa (see page 468, col. 1, paragraph 2; col. 2, paragraph 2, second half of paragraph).

34. Wirgtuin et al (1994) is cited to show associated with chronic neuropathies cross react with *Campylobacter jejuni* lipopolysaccharide.

35. Winsor et al (1986) is cited to show *Campylobacter jejuni* produces a 97 kDa antigen (see page 1220, Figure 1 and col. 2, first and second paragraphs)

36. Wirguin et al (1997) is cited to show *Campylobacter* lipopolysaccharide to induce antibodies directed to GM1 ganglioside antigen.

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. VGP July 20, 2001

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